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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,175	07/11/2001	Hau H. Doung	A-68718-3/RFT/RMS/RMK	1169

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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,175	DOUNG ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-52 and 54-65* is/are pending in the application.

4a) Of the above claim(s) *65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-52 and 54-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 12 August 2005 in which claims 42, 45, 49 and 65 were amended and claim 53 was canceled. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 12 April 2005 are maintained. Applicant's arguments have been thoroughly reviewed and are discussed below.

Claims 42-52 and 54-64 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 45-47, 55-57 and 60-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Lennox et al (U.S. Patent No. 6,461,490, filed 24 April 1997) as defined by Morris, C. ed (Academy Press Dictionary of Science and Technology, Academic Press, San Diego, 1992, page 1726).

Regarding Claim 45, Lennox et al disclose a biochip cartridge comprising a reaction chamber comprising a substrate comprising a printed circuit board comprising an array of

electrodes a self assembled monolayer and a capture binding ligand (Column 14, lines 33-42) wherein the ligand is covalently attached to the electrode film #50 (Column 8, lines 21-25; Column 10, lines 1-8; and Fig. 4-5) and a inlet port for reagent introduction and interconnects for electrical connections (Column 5, lines 12-60; Column 15, lines 12-30; and Fig. 1 and 13-14) wherein the binding ligands comprising nucleic acids (Column 8, lines 59-63).

It is noted that the specification defines the claimed circuit board as comprising a substrate coated with a conducting layer and process using photolithography (page 17, lines 27-30). Furthermore, the Academy Press Dictionary defines printed circuit board as "rectangular device onto which various chemical elements and substrates are laid down so that wiring can be applied". Lennox et al disclose the array of electrodes produced via photolithography (Column 14, lines 35-40). Hence, Lennox, disclose the printed circuit board as claimed.

Regarding Claim 46, Lennox et al disclose the biochip wherein the electrode is on a surface of the printed circuit board (Column 14, lines 35-40 and Fig. 14).

Regarding Claim 47, Lennox et al disclose the biochip wherein the electrode is fabricated on the surface via photolithography (14, lines 35-40 and Fig. 14).

Regarding Claim 55, Lennox et al disclose the biochip wherein the reaction chamber further comprises an outlet port (Column 5, lines 38-41).

Regarding Claim 56, Lennox et al disclose the biochip wherein the array is on one surface of the substrate (Column 14, lines 11-14).

Regarding Claim 57, Lennox et al disclose the biochip wherein two surfaces of the substrate comprise an array (Column 14, lines 11-14).

Regarding Claim 60, Lennox et al disclose the biochip wherein the binding ligands comprising proteins (Column 8, lines 59-63).

Regarding Claim 61, Lennox et al disclose the biochip comprising an assay complex comprising a binding ligand, target and electron transfer moiety i.e. ionic species (Column 11, lines 55-Column 12, line 35).

Regarding Claim 62, Lennox et al disclose the biochip wherein the monolayer comprises a conductive oligomer (Column 12, lines 13-16).

Regarding Claim 63, Lennox et al disclose the biochip wherein at least one electrode is gold (Column 14, lines 38-39).

Regarding Claim 64, Lennox et al disclose the biochip wherein the monolayer comprise a thiol forming species (Column 2, lines 48-51).

Response to Arguments

4. Applicant asserts that Lennox et al do not disclose the claimed covalently attached capture binding ligand because the reference does not teach the nucleic acid covalently attached. The argument has been considered but is not found persuasive. The claims are drawn to a capture binding ligand "comprising a nucleic acid" that is covalently attached to the electrode. As Applicant notes (page 7, third full paragraph of the response), Lennox teaches a capture binding ligand (HSP1) covalently attached wherein the covalently attached binding ligand "comprises" a nucleic acid via binding with a HSP2 protein (Column 8, lines 21-25 and 59-63; Column 10, lines 1-8; and Fig. 4-5). Hence, the capture ligand of Lennox comprises (via binding) a nucleic acid as claimed.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 42-44, 46-52, 54-58 and 60-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al (U.S. Patent No. 6,461,490, filed 24 April 1997) as defined by Morris, C. ed (Academy Press Dictionary of Science and Technology, Academic Press, San Diego, 1992, page 1726) in view of Anderson et al (U.S. Patent No. 6,326,211, filed 19 April 1999).

Regarding Claims 42 and 49, Lennox et al disclose a biochip cartridge comprising a reaction chamber comprising a substrate comprising an array of electrodes a self assembled monolayer and a capture binding ligand (Column 14, lines 33-42) wherein the ligand is covalently attached to the electrode film #50 (Column 8, lines 21-25; Column 10, lines 1-8; and Fig. 4-5) and a inlet port and an outlet port (Column 5, lines 37-41) and interconnects for electrical connections (Column 5, lines 12-60; Column 15, lines 12-30; and Fig. 1 and 13-14) and wherein the binding ligands comprising nucleic acids (Column 8, lines 59-63).

Lennox et al further teach the cartridge comprises inlet port and outlet port i.e. vent are provided to facilitate fluid flow through the chamber (Column 5, lines 38-41 and Column 11, lines 31-34) but they are silent regarding a semi-permeable membrane for the vent and positioning of the inlet port and vent.

However, Anderson teaches a similar cartridge comprising a biochip array, the cartridge comprising an inlet port (#110) and vent comprising a membrane filter (#118) (Column 20, lines 56-62 and Column 22, lines 6-28) wherein the inlet is positioned at the bottom of the chamber and the vent is positioned at the top of the chamber. Anderson et al further teach the arrangement of the outlet and vent facilitates selective movement of reagents within the chamber, permits gas within the chamber to be expelled upon regent introduction (Column 30, lines 30-67) and allows reagent mixing by letting bubbles within the chamber to exit upon reagent introduction (Column 3, lines 50-56).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the inlet and vent in the reaction chambers of Lennox et al by positioning the inlet at the bottom of the chamber and the vent at the top of the chamber as taught by Anderson et al. One of ordinary skill in the art would have been motivated to do so by the teaching of Anderson et al wherein they teach the arrangement facilitates selective movement of reagents within the chamber, permits gas within the chamber to be expelled upon regent introduction (Column 30, lines 30-67) and allows reagent mixing by letting bubbles within the chamber to exit upon reagent introduction (Column 3, lines 50-56).

Regarding Claims 43 and 44, Lennox et al disclose the chamber comprises an inlet port and vent (Column 11, lines 31-34) but are silent regarding the physical relationship of the port and vent.

Anderson teaches a similar cartridge comprising an inlet port (#110) and vent (#118) (Column 20, lines 56-62 and Column 22, lines 6-28) wherein the inlet and vent are separated by fluidically connected. Anderson et al further teach the arrangement of the outlet and vent facilitates selective movement of reagents within the chamber, permits gas within the chamber to be expelled upon regent introduction (Column 30, lines 30-67) and allows reagent mixing by letting bubbles within the chamber to exit upon reagent introduction (Column 3, lines 50-56).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the inlet and vent in the reaction chambers of Lennox et al by positioning the inlet at the bottom of the chamber and the vent at the top of the chamber as taught by Anderson et al. One of ordinary skill in the art would have been motivated to do so by the teaching of Anderson et al wherein they teach the arrangement facilitates selective movement of reagents within the chamber, permits gas within the chamber to be expelled upon regent introduction (Column 30, lines 30-67) and allows reagent mixing by letting bubbles within the chamber to exit upon reagent introduction (Column 3, lines 50-56).

Regarding Claim 46, Lennox et al disclose the biochip wherein the electrode is on a surface of the printed circuit board (Column 14, lines 35-40 and Fig. 14).

Regarding Claim 47, Lennox et al disclose the biochip wherein the electrode is fabricated on the surface via photolithography (14, lines 35-40 and Fig. 14).

Regarding Claim 48, Lennox et al disclose the biochip of Claim 24 comprising an outlet port (Column 11, lines 31-34) but are silent regarding a membrane filter. However, Anderson et al teach the similar chamber wherein the outlet port comprises a semi permeable membrane whereby gas is permitted to escape while maintaining fluid within the chamber (Column 22, lines 6-28). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the outlet vent of Lennox et al by addition of a semi permeable membrane as taught by Anderson et al for the expected benefit of allowing gas escape while maintaining the fluid (Column 22, lines 6-28).

Regarding Claim 50, Anderson et al teach the preferred semi permeable membrane comprises polytetrafluorethylene i.e. TEFLON (Column 22, lines14).

Regarding Claim 51, Anderson et al further teach the membrane allows escape of gas while retaining the sample fluid e.g. Teflon (Column 22, lines 6-17 and Fig. 2B) but they do not teach the permeable membrane is Gortex™. However, the specification teaches that Teflon and Gortex™ are functional equivalents (page 13, second paragraph).

> For example, a semi-permeable membrane or filter may be used, that preferentially allows the escape of gas but retains the sample fluid in the chamber. For example, porous teflons such as Gortex™ allow air but not fluids to penetrate.

The courts have stated with regard to homologs that the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904). Therefore, based on the functional equivalency of Teflon and Gortex™ one of ordinary skill in the art would have been motivated to

substitute Gortex™ for the Teflon of Anderson et al because one of ordinary skill would have expected the two membranes to function in an equivalent manner.

Regarding Claim 52, Lennox et al teach a printed circuit board. It is noted that the specification defines the claimed circuit board as comprising a substrate coated with a conducting layer and process using photolithography (page 17, lines 27-30). Furthermore, the Academy Press Dictionary defines printed circuit board as "rectangular device onto which various chemical elements and substrates are laid down so that wiring can be applied". Lennox et al disclose the array of electrodes produced via photolithography (Column 14, lines 35-40). Hence, Lennox, disclose the printed circuit board as claimed.

Regarding Claim 54, Lennox et al teach the chamber is designed to hold a solution (Column 1, lines 29-30) but they are silent regarding the presence of a gasket. However, Anderson et al teach the similar chamber for holding a solution wherein the chamber comprises a gasket (i.e. diaphragm) that retains fluid in contact with the array (Column 21, lines 35-60). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the diaphragm of Anderson et al to the chamber of Lennox et al for the expected benefit of sealing the reaction chamber as preferred by Anderson (Column 4, line 16-20 and Column 36, lines 53-55).

Regarding Claim 55, Lennox et al disclose the biochip wherein the reaction chamber further comprises an outlet port (Column 5, lines 38-41).

Regarding Claim 56, Lennox et al disclose the biochip wherein the array is on one surface of the substrate (Column 14, lines 11-14).

Regarding Claim 57, Lennox et al disclose the biochip wherein two surfaces of the substrate comprises an array (Column 14, lines 11-14).

Regarding Claim 58, Anderson et al teach the similar cartridge further comprising means a top (Column 16, lines 2-11) and at least one storage well comprising assay reagents (Column 24, lines 44-65 and Fig. 5 A & B) wherein the arrangement of storage wells adjacent to

the substrate provides easy access to reagents and convenient storage reagents (Column 25, lines 42-52). While they do not specifically teach the cap comprises the storage well, they clearly suggest such a configuration when they teach adjacent to and easy access. Furthermore, the courts have stated that a rearrangement of parts known in the art is a mere design choice and not patentable over the prior art parts. Therefore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the arrangement of cap and storage well to incorporate the storage well in the cap based on the desired adjacent arrangement providing convenient storage taught by Anderson et al (Column 25, lines 42-52).

> In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (Claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.); In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice) (MPEP 2144.04).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the cap comprising a storage well as taught by Anderson et al to the cartridge of Lennox et al for the expected benefits of easy access to reagents and convenient storage reagents as taught by Anderson et al (Column 25, lines 42-52).

Regarding Claim 60, Lennox et al disclose the biochip wherein the binding ligands comprising proteins (Column 8, lines 59-63).

Regarding Claim 61, Lennox et al disclose the biochip comprising an assay complex comprising a binding ligand, target and electron transfer moiety i.e. ionic species (Column 11, lines 55-Column 12, line 35).

Regarding Claim 62, Lennox et al disclose the biochip wherein the monolayer comprises a conductive oligomer (Column 12, lines 13-16).

Regarding Claim 63, Lennox et al disclose the biochip wherein at least one electrode is gold (Column 14, lines 38-39).

Regarding Claim 64, Lennox et al disclose the biochip wherein the monolayer comprise a thiol forming species (Column 2, lines 48-51).

7. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al (U.S. Patent No. 6,461,490, filed 24 April 1997) as defined by Morris, C. ed (Academy Press Dictionary of Science and Technology, Academic Press, San Diego, 1992, page 1726) and Anderson et al (U.S. Patent No. 6,326,211, filed 19 April 1999) as applied to Claim 9 above and further in view of Hayes et al (U.S. Patent No. 6,334,980, filed 25 September 1998).

Regarding Claim 59, Lennox et al describe the components of the cartridge (Column 1, lines 12-63 and Column 14, line 28-Column 15, line 31) but do not specifically teach the top is removable.

However, reaction chambers having removable covers were well known in the art at the time the claimed invention was made as taught by Hayes et al who specifically teach the removable cover permits addition of reagents to the chamber at desired times e.g. later (Column 12, lines 44-49). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the reaction chamber of Lennox et al by providing a removable cover as taught by Hayes et al for the expected benefit of permitting reagent addition as desired (Column 12, lines 44-49).

Response to Arguments

8. Applicant asserts that the combination of the cited references fail to teach all the claimed elements; the cited references fail to provide the motivation to combine; modifying the references would change the principle operation; and the cited references fail to suggest the

modification would have a reasonable expectation of success. All of these arguments are based on Applicant's assertion that Lennox et al do not teach the capture ligand as claimed. However, as stated above and reiterated below, Lennox et al do teach the claimed capture ligand.

The claims are drawn to a capture binding ligand "comprising a nucleic acid" that is covalently attached to the electrode. As Applicant notes (page 7, third full paragraph of the response), Lennox teaches a capture binding ligand (HSP1) covalently attached wherein the covalently attached binding ligand "comprises" a nucleic acid via binding with a HSP2 protein (Column 8, lines 21-25 and 59-63; Column 10, lines 1-8; and Fig. 4-5). Hence, the capture ligand of Lennox comprises (via binding) a nucleic acid as claimed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
October 12, 2005